K123397

510(K) SUMMARY
MULTILINK AUTOMIX

JAN 3 1 2013

Contact: Donna Marie Hartnett

Company: Ivoclar Vivadent, Inc. 175 Pineview Drive, Amherst, NY 14228
(716) 691-0010

Date Prepared: December 4, 2012

Proprietary Name: Multilink Automix

Classification Name: Material, Tooth Shade, Resin (872.3690)

Predicate Devices: Multilink (K032470)

Device Description: Multilink Automix is a self-curing and self-etching luting composite system for the adhesive luting of indirect restorations made of metal, metal-ceramic, all-ceramic and composite. Multilink Automix is applied together with the self-etching and self-0curing Multilink Primer. Monobond Plus is recommended as a coupling agent to achieve a strong bond to precious and non-precious alloys, as well as to all ceramics made of zirconium and aluminum oxide and silicate ceramics.

The predicate device to which Multilink Automix has been compared is Multilink (K032470). For this application, Multilink Automix has been compared to its predicate with regard to chemical composition, performance data and indications for use. The comparison shows that Multilink Automix is substantially equivalent to the predicate device.

Intended Use:

Multilink Automix is used for the permanent cementation of indirect restorations where a strong bond is desired:

- Inlays, onlays, crowns, bridges and root posts made of:
  - Metal and metal ceramics
  - All-ceramics, in particular opaque zirconium oxide ceramics
  - Composites and fibre-reinforced composites

Technological Characteristics: The device design, i.e. delivery form, and intended use of Multilink Automix and the predicate device are the same. The composition of the subject device has been modified from the predicate, however, there are no ingredients in the subject device which pose any new issues of safety and effectiveness.

Testing Summary: The device was tested in accordance with ISO 4049:2000 for Polymer based dental restorative materials for Water Absorption, Water solubility, radiopacity, Flexural Strength, Modulus of Elasticity, Compressive Strength and Shear Bond Strength and the results from testing demonstrates that Multilink Automix is substantially equivalent to the predicate device. Biocompatibility testing and evaluation was also carried out according to ISO 10993.

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The following table shows the performance data of Multilink Automix and its predicate device:

Property	UOM	Multilink (K032470)	Multilink Automix	Multilink Automix
			Self Curing	Dual Curing
Working time (37C)	Min	3-4	3-4	--
Setting time	Min	7-9	6-7	--
Film Thickness	µm	<20	<50	<50
Water Absorption	µg/mm^3	<25.0	<40	<40
Water solubility	µg/mm^3	<3.0	<7.5	<7.5
Radiopacity	%Al	350	350	350
Flexural Strength	MPa	90±10	70±20	110±10
Modulus of Elasticity	MPa	5000±1000	3250±400	6000±400
Compressive Strength	MPa	250±20	240±20	280±20
Transparency Base (trans and Cat) Yellow and Cat Opaque and Cat	%	 12±1.5 10±1.5 2±0.5	 12±1.5 10±1.5 2±0.5	 12±1.5 10±1.5 2±0.5
Vickers Hardness	MPa	370	--	440±30
Shear Bond Strength Dentin / 24h Enamel/ 24hh	MPa	 21±2 23±4	 17±5 18±3	 21±2 23±4

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 31, 2013

Ivoclar Vivadent, AG
C/O Ms. Donna Marie Hartnett
Director of Quality Assurance / Regulatory Affairs
Ivoclar Vivadent, Incorporated
175 Pineview Drive
AMHEREST NY 14228

Re: K123397
Trade/Device Name: Multilink Automix
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: October 31, 2012
Received: November 5, 2012

Dear Ms. Hartnett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

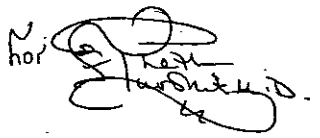
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123397

Device Name: Multilink Automix

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Susan Runner DDS, MA 2013.01.30 15:42:28 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

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